UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
_____	)	_____
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") _____the chemical substance _____("the PMN substance") submitted by_____("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

COMMENT 1/14/08 3:30 PM
Comment: [DELETE INAPPLICABLE ENTRIES; LETTER REMAINING ENTRIES WITH LOWER CASE LETTERS]

(1) not manufacture or import the PMN substance unless the PMN substance is manufactured _____.

(2) analyze representative samples to ensure compliance with number (1), and,

(3) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Chemical Identity:

Specific:

Generic:

Use:

Specific:

Generic:

Maximum 12-Month Production Volume:

Test Data Submitted with PMN:

IV. EPA'S ASSESSMENT OF RISK

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption:

Toxicological Endpoints of Concern:

Basis:

[Note to Program Managers: If concern for the PMN substance is based on a chemical category of concern, include the following reference to the New Chemicals Chemical

Category Website.]

See www.epa.gov/opptintr/newchems/pubs/chemcat.htm

Environmental Effects Summary:

[Note to Program Managers: If concern for the PMN substance is based on a chemical category of concern, include the following reference to the New Chemicals Chemical Category Website.]

See www.epa.gov/opptintr/newchems/pubs/chemcat.htm

Exposure and Environmental Release Summary:

	Manufacture	Process	Use	Consumer
# Sites				
Workers (#/site)				
Exposure (days/year)				
Dermal Exposure (mg/day)				
Inhalation Exposure (mg/day)				
Drinking Water Exposure (mg/day)				
Releases (days/year)				
Release to Water (kg/day)				

Risk to Workers:
[Note to Program Managers: Give statement on MOE or cancer risk.]

NIOSH Assigned Protection Factor ("APF"):

New Chemical Exposure Limit: ____ as an 8-hour time-weighted average ("TWA").

Risk to General Public:

Risk to Consumers:

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health effects from exposure to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance.

(b) In light of the potential risk of human health effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

Pending Testing. The following additional information would be required to evaluate the following effects which may be caused by the PMN substance:

Information	Effects	Guidelines

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

COMMENT 1/14/08 3:30 PM

Comment: [DELETE THOSE ACTIVITY RESTRICTIONS WHICH ARE NOT DEPENDENT UPON THE PENDING TESTING. FOR EXAMPLE, IF THE PENDING TESTING IS FOR ECOTOXICITY, THEN THE ONLY ACTIVITY RESTRICTIONS WHICH WILL REMAIN IN EFFECT PENDING THAT TESTING AND SHOULD BE LISTED HERE ARE THE DISPOSAL RESTRICTIONS.]

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance _____ (P-__-____)("the PMN substance") in the United States by _____ ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured) or _____.

[Note to Program Managers: If applicable to the specific PMN substance, identify a state or

states in which exposure to the PMN substance no longer presents a significant risk, e.g., "incorporated into a polymer matrix", "adhered onto film", or similar.]

(2) De Minimis Concentrations. The requirements of this Order do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If his Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(3) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(4) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(5) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(6) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(7) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Chemical Restriction. The Company shall not manufacture or import the PMN substance, unless the PMN substance is manufactured from _____.

(b) Analysis. The Company shall analyze representative samples of the PMN substance to determine compliance with the requirements in paragraph (a) using _____. The Company shall analyze the structure of the _____to determine that the PMN substance is _____at each manufacturing facility both (1) at the time of initial commencement of non-exempt manufacture at that facility or upon initial import, and (2) at least annually thereafter during every year in which the PMN substance is manufactured at that facility or imported. If the PMN substance is imported, the Company shall obtain from the foreign manufacturer written documentation to certify that representative samples of the PMN

substance have been analyzed, consistent with the requirements of this paragraph (b), and determined to comply with the requirements in paragraph (a).

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

COMMENT 1/14/08 3:30 PM
Comment: [INCLUDE PARAGRAPH (a) IN ALL ORDERS. THERE IS NO CORRESPONDING SNUR PROVISION FOR PARAGRAPH (a).]

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture or import the PMN substance:

COMMENT 1/14/08 3:30 PM
Comment: [MAKE SURE PUNCTUATION IS CORRECT IN FOLLOWING SECTIONS]

(1) unless the PMN substance is _____.

TESTING

(a) Section 8(e) Reporting. Any information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

COMMENT 1/14/08 3:30 PM
Comment: [INCLUDE PARAGRAPHS (a), (b) and (c) IN ALL ORDERS. INCLUDE THE ENTIRE TESTING SECTION IN ANY ORDERS WITH TRIGGERED TESTING. THE CORRESPONDING SNUR CITATION FOR TRIGGERED TESTING IS THE PRODUCTION VOLUME LIMIT AT 721.80(P) FOR NON-CBI PRODUCTION VOLUMES AND 721.80(q) FOR CBI VOLUMES. IN ADDITION, FOR THE SNUR, YOU MUST SPECIFY THE SNUR PRODUCTION VOLUME LIMIT. FOR TIERED TESTING, THE SNUR VOLUME LIMIT SHOULD BE THE LOWEST PRODUCTION VOLUME IN PARAGRAPH (d) OF THE CONSENT ORDER TESTING SECTION.]

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order (including studies identified in section VI. of the Preamble), or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be

performed pursuant to this Order (including studies identified in section VI. of the Preamble) must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (d)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (d)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of

any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

COMMENT 1/14/08 3:30 PM
Comment: [INCLUDE THOSE Record-keeping PROVISIONS WHICH CORRESPOND TO THE SUBSTANTIVE REQUIREMENTS IN THE BODY OF THE CONSENT ORDER. SUBPARAGRAPH (a)(1), PRODUCTION VOLUME, SHOULD BE INCLUDED IN ALL ORDERS WITH TESTING TRIGGERS AND/OR DISPOSAL OR RELEASE TO WATER RESTRICTIONS.]

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any

amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(a) & (b)]

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(c)]

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(d)]

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

COMMENT 1/14/08 3:30 PM
Comment:
[721.125(e)]

(7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

(8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(f)]

(9) Copies of labels required under the Hazard Communication Program section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(g)]

(10) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(h)]

(11) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [DELETE THOSE ACTIVITIES FOR WHICH THERE ARE NO CORRESPONDING SUBSTANTIVE REQUIREMENTS IN THE BODY OF THE ORDER]

(12) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(i)]

COMMENT 1/14/08 3:30 PM
Comment: [721.125(j)]

(13) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

COMMENT 1/14/08 3:30 PM
Comment: [721.125(k)]

(14) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(15) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured or imported.

COMMENT 1/14/08 3:30 PM
Comment: [NA]

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities

of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken,

or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental

effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

_____ _____

Date

Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

_____ _____

Date

Name:

Title:

Company:

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

COMMENT 2/6/08 10:19 AM
Comment: [ALL RBH ORDERS WITH PROTECTIVE EQUIPMENT REQ'TS]

"Company" means the person or persons subject to this Order.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

COMMENT 2/6/08 10:19 AM
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS WORD]

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

COMMENT 2/6/08 10:19 AM
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS WORD]

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

COMMENT 2/6/08 10:19 AM
Comment: [RBH OR RBE ORDERS WITH USE OR DISTRIBUTION SECTIONS CITING THIS PHRASE]

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS WITH CONTRACT MANUFACTURER PROVISIONS]

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

COMMENT 2/6/08 10:19 AM
Comment: [RBH ORDERS WITH DERMAL PROTECTION REQ'TS]

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

COMMENT 2/6/08 10:19 AM
Comment: [RBH OR RBE ORDERS WITH DISPOSAL RESTRICTIONS]

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

COMMENT 2/6/08 10:19 AM
Comment: [RBH ORDERS W/ RESPIRATOR REQ'TS]

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

COMMENT 2/6/08 10:19 AM
Comment: [RBH AND RBE ORDERS WITH MANUFACTURING, USE, OR DISTRIBUTION REQUIREMENTS CITING THIS PHRASE]

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

COMMENT 2/6/08 10:19 AM
Comment: [RBH AND RBE ORDERS WITH MANUFACTURING, USE, OR DISTRIBUTION REQUIREMENTS CITING THIS PHRASE]

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

COMMENT 2/6/08 10:19 AM
Comment: [RBH ORDERS WITH PERSONAL PROTECTIVE EQUIPMENT REQ'TS]

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

COMMENT 2/6/08 10:19 AM
Comment: [RBH AND RBE ORDERS WITH DISPOSAL RESTRICTIONS]

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS WITH TESTING TRIGGERS]

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS WITH TESTING TRIGGERS]

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

COMMENT 2/6/08 10:19 AM
Comment: [RBH AND RBE ORDERS WITH DISPOSAL RESTRICTIONS]

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

COMMENT 2/6/08 10:19 AM
Comment: [RBH AND RBE ORDERS W/ RELEASE TO WATER PROVISIONS]

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

"Workplace" means an establishment at one geographic location containing one or more work areas.

COMMENT 2/6/08 10:19 AM
Comment: [ALL ORDERS]

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official	Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone